SECTION 7 - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

NAVIAID™ ICVI DEVICE

510(k) Number K110291

Applicant's Name:

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Name of the device:

NaviAid™ ICVI device

Trade or proprietary name, if applicable:

NaviAid™ ICVI device

Common or usual name:

NaviAid™ ICVI Device

Establishment Registration No.:

3005261802

Classification Name:

Endoscope and accessories

Classification:

FDA has classified Endoscope and accessories devices as a Class II medical device, with product code ODC and 21 CFR classification code 876.1500. Review by the Gastroenterology/Urology Devices Panel.

Predicate Device:

The new NaviAid™ ICVI device is substantially equivalent to the previously cleared NaviAid™ ICVI device (manufactured by Smart Medical Systems Ltd. and the subject of 510(k) document no. K101191). A comparison table and detailed discussion are presented in Section 10 of this application.

Device Description:

The NaviAid™ ICVI is an on-demand disposable that is inserted through the instrument channel of the endoscope in order to enable advancement and positioning of a standard endoscope in the small intestine.

The NaviAid™ ICVI system comprises a disposable balloon system and an Air Supply Unit ("ASU") or a Single Balloon - Air Supply Unit ("SB ASU") for inflating and deflating the balloon system.

Since the ASU was initially designed to support the BGE device (manufactured by Smart Medical Systems and the subject of K060923) which includes 2 balloons, the ASU includes 2 air ports. By closing 1 port using a standard stopcock the ASU is also used for the operation of a single balloon device such as the ICVI. In order to improve user's convenience and ease of use, several modifications were applied to the ASU so that it could support only a single balloon system (the new ASU is referred to as the Single Balloon - Air Supply Unitor "SB ASU"). Both the ASU and the SB ASU are compatible with the ICVI and the SB ASU will be an alternative component to the ASU.

The role of the ICVI disposable is to facilitate advancement of a standard endoscope into the small intestine. The NaviAid™ ICVI disposable includes the ICVI Balloon and the

ICVI inflation tube. The balloon is inflated by ambient air. The ASU or SB ASU operate and control the inflation and deflation of the balloon through a foot-pedal. The balloon is connected to a dedicated inflation tube that runs inside the instrument channel of the endoscope, and is connected at its proximal (user) end to the ASU or SB ASU.

The ICVI balloon can be advanced ahead of the endoscope tip or pulled back through pushing/pulling action on the ICVI inflation tube at its proximal side, outside the patient's body. When the ICVI balloon is advanced and then inflated, it functions as a distal anchor, to which the endoscope tip is advanced, and the ICVI inflation tube serves as a rail that leads the endoscope as it is pushed towards the anchoring ICVI balloon.
The balloon and tube negligibly compromise the endoscope's flexibility, or its field of view. Additionally, the ICVI disposable negligibly compromise the maneuverability of the endoscope's tip and does not limit the usage of any standard endoscopy tools, such as biopsy forceps, snare, needle etc. though not simultaneously while the device is applied.
The NaviAid™ ICVI disposable is intended for single use, while the ASU and SB ASU are re-usable.

Intended Use / Indication for Use:

The NaviAid™ ICVI device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope in the small intestine (i.e., an endoscope that has an instrument channel that is at least 3.7mm and is used for standard intestinal endoscopic visualization).

Comparison of Technological Characteristics with the predicate device:

The SB ASU is an alternative component to the ASU, which is able to support and control the air flow into/out of a single balloon device which may be connected to it. Though, the Air Supply Unit (ASU) can support two balloons, it comprises two identical independent paths; each one of them controls one balloon. Once operated with a single balloon device (such as the NaviAid™ ICVI), the ASU is active in one air path only, while the other is idle throughout the procedure. Thus, it is relevant to compare the SB ASU with one air control path of the ASU. The two mechanisms are very similar, they both comprise vacuum and pressure sensors, an electrically controlled valve, which is opened and closed based on pressure readings, and a mechanical relief valve that is

designed to relive excess pressure. Not only do these components exist in both mechanisms, these components are identical in both systems. The difference between the two systems arises only from the source of air flow. While the ASU comprises a tank which introduces compressed air into the balloon or extracts the air out of the balloon (using a piston), the SB ASU comprises two air pumps, one introduces air towards the balloon and the other extracts air out of it, in other words, air pump and vacuum pump. The pressure control algorithm is also very similar between the two systems. The operation of both is based on pressure sensor readings and opening and closing the electric valve based on these readings. Nevertheless, some differences do arise due to the difference in air flow source. Therefore a new electrical control board and new software were designed. Thus, electrical and mechanical safety and EMC tests were performed and the new software was validated. In summary, the ASU and the SB ASU comprise identical critical components which are operated in very similar way. The difference arises only due to the source of pressure/vacuum and thus some algorithmic changes were required. These changes were validated as part of the development process.

The ICVI disposable was not changed or altered.

Non-Clinical Performance Data

The performance tests include testing of the modified NaviAid™ ICVI Device with the new SB ASU component. All tests relating to the ICVI disposable are located in the original submission of the ICVI Device (K101191) and not repeated here, as this component was not changed.

Performance tests relating to the SB ASU component are provided in detail in section 11. The following performance tests were conducted on the modified NaviAid™ ICVI device with the new SB ASU component:

1. SB ASU Performance Test (Doc. No. TP330001)
2. Electrical & Mechanical Safety Testing (according to IEC 60601-1)
3. Electromagnetic Compatibility Testing (according to IEC 60601-1-2)
4. Software Validation (according to IEC 60601-1-4 & FDA Guidelines)

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The non-clinical tests demonstrated that the modified NaviAid™ ICVI device with the new SB ASU component meets its design and performance specifications. The NaviAid™ ICVI device may be safely and effectively used in procedures in order to ensure the positioning of a standard endoscope in endoscopy of the small intestine and reach depths of the intestine that may not otherwise be accessible with a standard endoscope device.

Substantial Equivalence:

In summary, the new SB ASU component is a direct derivative of the ASU component. The intended use, basic technology, principle of operation specifications and safety requirements are similar. The difference in the source of air flow does not raise any new questions of safety and effectiveness. Consequently, the SB ASU component is substantially equivalent to the ASU and therefore, the modified NaviAid™ ICVI device is substantially equivalent to the previously cleared NaviAid™ ICVI device.

Performance Standards:

The modified NaviAid™ ICVI device with the new SB ASU component has been retested and complies with the following voluntary recognized standards:

1. Electrical & Mechanical Safety Testing (IEC 60601-1)
2. Electromagnetic Compatibility Testing (IEC 60601-1-2)
3. Software Validation (IEC 60601-1-4 & FDA Guidelines)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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JUN 17 2011

Re: K110291
Trade/Device Name: NaviAid™ ICVI Device
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: May 19, 2011
Received: May 20, 2011

Dear Ms. Yoselzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110291

Device Name: NaviAid™ ICVI Device

Indications for use:

The NaviAid™ ICVI device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope in the small intestine (i.e., an endoscope that has an instrument channel that is at least 3.7mm and is used for standard intestinal endoscopic visualization).

Prescription Use ___√___ OR Over-The-Counter Use___
(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carolyn Y Neuland for Herb Lerner, MD.
(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110291